

Patent Claims

See 15

1. Liquid formulation which comprises human interferon- β as active ingredient in a concentration of up to 25 MU/ml and a buffer for setting a pH of 5 to 8, is free from human serum albumin and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.

2. Liquid formulation which comprises human interferon- β as active ingredient and a buffer for setting a pH of 6 to 7.2, is free from human serum albumin and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.

3. Liquid formulation which comprises human interferon- β as active ingredient, a buffer for setting a pH of 5 to 8, and one or more amino acids and shows a long-term stability of the biological activity (in vitro) of at least 80% of the initial activity after storage for 3 months at 25°C.

4. Formulation according to Claim 1,
characterized in that
it comprises a glycosylated interferon- β .

5. Formulation according to Claim 2,
characterized in that
the interferon- β originates from CHO cells.

C 6. Formulation according to *claim 1*,
characterized in that

claim 1

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it comprises the buffer in a concentration of 10 mmol/l to 1 mol/l.

7. Formulation according to ~~any of Claims 1 to 6~~,
characterized in that
it comprises a buffer selected from the group consisting of phosphate, citrate and acetate buffers and mixtures of these.

10 8. Formulation according to Claim 7,
characterized in that
it comprises a phosphate/citrate buffer.

C 9. Formulation according to ~~any of Claims 1 and 3 to 8~~,
characterized in that
it has a pH between 6 and 7.2.

10. Formulation according to Claim 3,
characterized in that
it is free from human serum albumin.

C 11. Formulation according to ~~any of Claims 1 to 10~~,
characterized in that,
apart from the active ingredient, it is free from human or animal polypeptides.

C 12. Formulation according to ~~any of Claims 1 to 11~~,
characterized in that
it is free from surfactants.

C 13. Formulation according to ~~any of Claims 1 to 12~~,
characterized in that
it exhibits a chemical integrity after storage for 6 months at 25°C.

C 14. Formulation according to ~~any of Claims 1 to 13~~,
characterized in that

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it exhibits a physical integrity after storage for 6 months at 25°C.

C 15. Formulation according to ~~any of Claims 1, 2 and 4 to 14,~~ *claim 1* characterized in that it furthermore comprises one or more amino acids.

C 16. Formulation according to Claim 3 ~~or 15,~~ characterized in that it comprises methionine.

15 17. Formulation according to Claim 16, characterized in that the methionine is present in a concentration of 0.1 to 4 mmol/l.

C 18. Formulation according to ~~any of Claims 1 to 17,~~ *claim 1* characterized in that it furthermore comprises auxiliaries for adjusting the tonicity.

C 19. Formulation according to ~~any of Claims 1 to 18,~~ *claim 1* characterized in that it furthermore comprises thickeners for increasing the viscosity

C 20. Formulation according to ~~any of Claims 1 to 19,~~ *claim 1* characterized in that it furthermore comprises physiologically acceptable preservatives.

C 21. Pharmaceutical preparation, characterized in that

35 C it comprises a liquid formulation according to ~~any of Claims 1 to 20.~~ *claim 1*

22. Pharmaceutical preparation according to Claim 21 for oral, parenteral or ophthalmological administration.

5 C 23. Pharmaceutical preparation according to Claim 21
C ~~or 22~~ with unit doses of 1 to 25 MU.

10 24. Process for the preparation of a pharmaceutical preparation according to any of Claims 21 to 23,
~~characterized in that~~

a formulation according to any of Claims 1 to 20 and, if appropriate, other pharmaceutical formulation auxiliaries which are necessary is prepared and formulated as a suitable dosage form.

15 25. Process for improving the shelf life of a liquid formulation which comprises human interferon- β as active ingredient and a buffer for setting a pH of 5 to 8,

20 ~~characterized in that~~
a formulation without human serum albumin or/and with one or more amino acids is used.

25 26. Process according to Claim 25,

~~characterized in that~~
the improved shelf life encompasses improved long-term stability of the biological activity (in vitro), of the chemical integrity or/and of the physical integrity.

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